

WE CLAIM:

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1. An isolated or recombinant immunogenic polypeptide which comprises, mimics or cross-reacts with a B-cell or T-cell epitope of a *Lawsonia spp.* OmpH polypeptide.
 2. The isolated or recombinant immunogenic polypeptide of claim 1 capable of eliciting the production of antibodies against *Lawsonia spp.* when administered to an avian or porcine animal.
 3. The isolated or recombinant immunogenic polypeptide of claim 1 capable of conferring a protective immune response against *Lawsonia spp.* when administered to an avian or porcine animal.
 4. The isolated or recombinant immunogenic polypeptide of claim 2 wherein the *Lawsonia spp.* is *L. intracellularis*.
 5. The isolated or recombinant immunogenic polypeptide of claim 3 wherein the *Lawsonia spp.* is *L. intracellularis*.
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 6. An isolated or recombinant immunogenic polypeptide selected from the following:
 - (i) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 70% sequence identity overall to the amino acid sequence set forth in SEQ ID NO: 1;
 - (ii) a homologue, analogue or derivative of (i) which mimics a B-cell or T-cell epitope of a *Lawsonia spp.* OmpH polypeptide.
 7. The isolated or recombinant immunogenic polypeptide of claim 6 capable of eliciting the production of antibodies against *Lawsonia spp.* in a porcine or avian animal.
 8. The isolated or recombinant immunogenic polypeptide of claim 7 capable of conferring a protective immune response against *Lawsonia spp.* in a porcine or avian animal.

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9. The isolated or recombinant immunogenic polypeptide of claim 8, capable of inducing humoral immunity against *Lawsonia spp.* in a porcine or avian animal.

Sub A4 10. The isolated or recombinant immunogenic polypeptide of claim 9, capable of inducing humoral immunity against *Lawsonia spp.* in a porcine animal.

11. The isolated or recombinant immunogenic polypeptide of claim 8 wherein the *Lawsonia spp.* is *L. intracellularis*.

12. The isolated or recombinant immunogenic polypeptide of claim 10 wherein the *Lawsonia spp.* is *L. intracellularis*.

Sub A5 13. The isolated or recombinant immunogenic polypeptide of claim 6 that comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the OmpH-encoding nucleotide sequence of pALK13 (ATCC 207196) and is capable of eliciting the production of antibodies against *Lawsonia intracellularis* when administered to an avian or porcine animal.

14. The isolated or recombinant immunogenic polypeptide of claim 13 that consists essentially of the amino acid sequence of SEQ ID NO: 1 or the amino acid sequence encoded by the OmpH-encoding nucleotide sequence of pALK13 (ATCC 207196) .

15. The isolated or recombinant immunogenic polypeptide of claim 13 or 14 capable of inducing a protective immune response against *Lawsonia intracellularis* in a porcine or avian animal.

16. The isolated or recombinant immunogenic polypeptide of claim 15 capable of inducing a protective immune response against *Lawsonia intracellularis* in a porcine animal.

Sub A6 17. A vaccine composition for the prophylaxis or treatment of infection of an animal by *Lawsonia spp.*, said vaccine composition comprising an immunogenic component

which comprises an isolated or recombinant polypeptide having at least about 70% sequence identity overall to the amino acid sequence set forth in SEQ ID NO: 1 or an immunogenic homologue, analogue or derivative thereof which is immunologically cross-reactive with *Lawsonia intracellularis*; and one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

18. The vaccine composition according to claim 17 wherein the *Lawsonia spp.* is *L. intracellularis*.

19. The vaccine composition according to claim 18 wherein the immunogenic component comprises an isolated or recombinant polypeptide that comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the OmpH-encoding nucleotide sequence of pALK13 (ATCC 207196).

20. The vaccine composition of claim 19, wherein the immunogenic component consists essentially of the amino acid sequence of SEQ ID NO: 1.

21. A combination vaccine composition for the prophylaxis or treatment of infection of an animal by *Lawsonia spp.*, said vaccine composition comprising:

- (i) a first immunogenic component which comprises an isolated or recombinant polypeptide having at least about 70% sequence identity overall to the amino acid sequence set forth in SEQ ID NO: 1 or an immunogenic homologue, analogue or derivative thereof which is immunologically cross-reactive with *Lawsonia intracellularis*;
- (ii) a second immunogenic component comprising an antigenic *L. intracellularis* peptide, polypeptide or protein; and
- (iii) one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

22. A vaccine vector that comprises, in an expressible form, an isolated nucleic acid molecule having a nucleotide sequence that encodes an isolated or recombinant immunogenic polypeptide which comprises the amino acid sequence set forth in SEQ

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ID NO: 1, such that said immunogenic polypeptide is expressible at a level sufficient to confer immunity against *Lawsonia spp.*, when administered to a porcine or avian animal.

23. The vaccine vector of claim 22 wherein the immunogenic polypeptide is expressed using the steps of:

- (i) placing an isolated nucleic acid molecule which comprises the nucleotide sequence set forth in SEQ ID NO: 2 or degenerate variant, a homologue, analogue or derivative thereof which has at least about 70% sequence identity thereto, in operable connection with a promoter sequence;
- (ii) introducing the isolated nucleic acid molecule and promoter sequence of step (a) into the vaccine vector; and
- (iii) incubating, growing, or propagating the vaccine vector for a time and under conditions sufficient for expression of the immunogenic polypeptide encoded by said nucleic acid molecule to occur.

24. The vaccine vector of claim 23 wherein the *Lawsonia spp.* is *L. intracellularis*.

25. A polyclonal or monoclonal antibody molecule that is capable of binding specifically to a OmpH polypeptide or a derivative of a OmpH polypeptide that is derived from *Lawsonia spp.* and has at least about 70% sequence identity overall to the amino acid sequence set forth in SEQ ID NO: 1.

26. The antibody molecule of claim 25 wherein the OmpH polypeptide or derivative thereof comprises the amino acid sequence set forth in SEQ ID NO: 1.

27. A method of diagnosing infection of a porcine or avian animal by *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising the steps of contacting a biological sample derived from said animal with the antibody molecule of claim 25 for a time and under conditions sufficient for an antigen:antibody complex to form, and then detecting said complex formation.

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28. The method of claim 27 wherein the biological sample comprises whole serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces or a rectal swab derived from a porcine animal.

29. A method of identifying whether or not a porcine or avian animal has suffered from a past infection, or is currently infected, with *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising contacting blood or serum derived from said animal with the immunogenic polypeptide of claim 1 for a time and under conditions sufficient for an antigen:antibody complex to form and then detecting said complex formation.

30. An isolated nucleic acid molecule which comprises a sequence of nucleotides which encodes, or is complementary to a nucleic acid molecule that encodes, a peptide, oligopeptide or polypeptide selected from the group consisting of:

- (i) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 70% sequence identity overall to the amino acid sequence set forth in SEQ ID NO: 1; and
- (iii) a homologue, analogue or derivative of (i) which mimics a B-cell or T-cell epitope of *Lawsonia spp.*

31. The isolated nucleic acid molecule of claim 30, wherein the peptide, oligopeptide or polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the OmpH-encoding nucleotide sequence of pALK13 (ATCC 207196) or a B-cell epitope or T-cell epitope thereof.

32. The isolated nucleic acid molecule of claim 31 comprising the nucleotide sequence set forth in SEQ ID NO: 2 or a complementary nucleotide sequence thereto, or a degenerate variant thereof.

33. The isolated nucleic acid molecule of claim 32 consisting essentially of the nucleotide sequence of SEQ ID NO: 2 or a degenerate variant thereof.

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34. A method of detecting *Lawsonia intracellularis* or related microorganism in a biological sample derived from a porcine or avian animal subject, said method comprising the steps of hybridising one or more probes or primers derived from the nucleotide sequence set forth in SEQ ID NO: 2 or a complementary nucleotide sequence thereto to said sample and then detecting said hybridisation using a detection means.
35. The method of claim 34 wherein the biological sample comprises whole serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces or a rectal swab derived from a porcine animal.
36. The method of claim 34 wherein the detection means comprises any nucleic acid based hybridisation or amplification reaction.
37. A probe or primer having at least about 15 contiguous nucleotides in length derived from SEQ ID NO: 2 or a complementary nucleotide sequence thereto.
38. A plasmid designated pALK13 (ATCC Accession No. 207196).
39. The combination vaccine according to claim 21 wherein the second immunogenic component comprises an antigenic *L. intracellularis* peptide, polypeptide or protein selected from the group consisting of SodC, FlgE, hemolysin and autolysin.

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